REMARKS

A. Status of the Claims

Applicants have amended claims 1, 19, and 29. Claim 14 was cancelled. Applicants note that support for the amended claims can be found in the specification at least on page 3, lines 17-31, and in the originally filed claims. No new matter has been added.

B. Examiner Interview

An interview with the examiner was conducted on September 15, 2009 to discuss the outstanding rejections of the pending claims, particularly the enablement rejection. While there was no resolution regarding the rejection, Applicants' representative sincerely appreciate the Examiner's time in discussing this matter.

C. Species Election

Applicants respectfully request reconsideration of the species election set forth in the Office Action mailed March 18, 2009 and maintained in the current Action. The species election requested that Applicants "elect one of the single disclosed species described in the paragraph bridging pg 3-4 for prosecution on the merits to which claims shall be restricted if no generic claim is finally held to be allowable. Currently all the claims are generic." Page 3 of Office Action mailed March 18, 2009.

Applicants elected, with traverse, the 11.5 kb fragment spanning nucleotides 49485 to 61006 of SEQ ID NO:1. Applicants previously argued that the species on the paragraph bridging pg 3-4 "are contained in the same upstream sequence and overlap with one another." Page 7 of Response filed April 17, 2009.

The current Action states that "the species claimed do not have a common element." It further says, "The claims and specification do not teach the smallest fragment disclosed (143 nucleotides of 55668-55810 of SEQ ID NO:1) was common to all of the fragments claimed.

A detailed explanation of the specification demonstrates that the smallest fragment is contained in all of the fragments specified in the paragraph bridging pg 3-4.

As shown below, each of the 8 segments contains the smallest fragment, which is from position 55668 – 55810 of SEQ ID NO:1. The fragment 55668-55810 is contained within each of the fragments listed.

49485 – 61006 (11.5 kb)
49485 – 57111 (7.6 kb)
49485 – 55810 (6.3 kb)
54807 – 57110, 57945 – 61006 (6.2 kb-GFP)
51389 – 55810 (4.4 kb)
52199 – 56423 (4.2 kb)
53820 – 55810 (1.9 kb)
54755 – 55810 (0.96 kb)
55668 – 55810 (44 nt)

Furthermore, except for the 6.2 kb fragment, this is also depicted in FIG. 1, which is attached as Exhibit 1. The smallest fragment is in all the other fragments shown in FIG. 1 and the 11.5 kb fragment contains each of the other fragments listed in the paragraph bridging page 3-4. It is not correct that the smallest fragment is not "common" to all the fragments claimed, as alleged in the Action. Accordingly, Applicants respectfully request reconsideration of the election because the searches would not be "materially distinct and separate."

Claims 1, 4, 6-12, 14-23, 29-35, 37, and 39-40 read on the elected species. Applicants erroneously marked claim 40 as "withdrawn" in the response to the restriction requirement. Applicants respectfully request that it be examined with the pending claims.

D. Claims Are Enabled

The Action rejects claims 1, 4, 6-12, 14-23, 29-35, 37, 39 (and presumably 40) as failing to comply with the enablement requirement. It contends that the claims as examined relate to an s-ship promoter comprising nucleotides 49485-61006 of SEQ ID NO:1 (the 11.5 kb fragment). It argues that the specification does not provide adequate guidance for those of skill in the art to make the 11.5 kb GFP construct. It contends that the specification indicates the 11.5 kb GFP construct was made from separate plasmids containing two halves of the proposed s-ship promoter region, but that there is not enough guidance regarding the "two halves," "the proposed

s-ship promoter region" or other elements other than the nucleic acid sequence encoding by GFP. The Action concludes that the "applicants do not enable those of skill to make or use the 11.5 kb fragment of nucleotides 49485-61006 of SEQ ID NO:1 (SEQ ID NO:5). Applicants respectfully traverse this rejection.

Applicants are unaware of any case that supports an enablement attack of a specific nucleic acid sequence when the entire sequence information is provided. SEQ ID NO:1 provides the sequence information, as does SEQ ID NO:5 (SEQ ID NO:5 is intended to be the same as 49485-61006 of SEQ ID NO:1) (Exhibit 2). A person of ordinary skill in the art could have such a fragment synthesized by a company, which would not constitute undue experimentation. That such an approach may or may not be expensive or impractical is not an issue that is relevant to enablement. "The specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" MPEP 2164.08 (citing *In re Wright*, 999 F.2d 1557, 1561, 27 U.S.P.Q. 1510, 1513 (Fed. Cir. 1993)). Obtaining a known sequence (based on the sequence provided in the specification) does not constitute "undue experimentation." Providing the full sequence of the recited fragment is sufficient to enable a person of ordinary skill in the art with respect to that fragment. Applicants respectfully request that this rejection be withdrawn.

Additionally and separately, the specification provides an example entitled "Construction of the 11.5kb- and 6.2kb-GFP *s-ship* promoter transgenes." Such an example is not *per se* required. "The specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation." MPEP 2164.02. Given the sequence information discussed above, this example in the specification provides details that a skilled person can use to clone the 11.5 kb region in the same manner as the applicants, even though this is not necessarily required. In that example, the following explanation is provided:

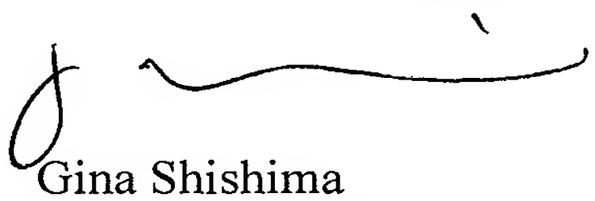
> The 11.5kb-GFP transgenic construct was prepared from two separate plasmids containing the two halves of the proposed *s-SHIP* promoter region, plus an 833 nt sequence from a lambda genomic clone, which was inserted between these two halves. The genomic organization of SHIP1 is shown in Wolf *et al.* (2000). The starting genomic clone contained a 4 kb region from the SacI site near the 3' end of the 7.6 kb genomic clone in intron 6, extending through exon 8 and into intron 8. This SacI-SacI fragment was cloned into the SacI site of pBluescript SK (pBSK). The GFP gene from pEGFP-1 (Invitrogen/Clontech) was excised with NcoI (encompassing the ATG translation start site of GFP) and SspI. This was ligated into the NcoI (the putative s-SHIP translation start site in exon 7) and EcoRV sites of the pBSK-4kb

clone. Next, the 5' half of the genomic promoter was added in the form of the SacI-SacI 7.6 kb genomic sub-clone. This was inserted into the one remaining SacI site at the 5' end of the intron 6-exon 7-GFP clone in pBSK. This left a gap of 0.9 kb between the two SacI sites in intron 6 (see Wolf *et al.*, 2000). This region was recovered as a larger BsiWI-EcoRI 2117 nt fragment, whose sequence demonstrated the insertion of 833 nucleotides between two SacI sites. Therefore, this BsiWI-EcoRI fragment was inserted into the same unique sites of the transgenic construct to produce the finished 11.5kb-GFP transgene in pBSK.

Page 70, lines 15-31 (emphasis added). FIGs. 1 and 3A further provide information that supports the description of how the 11.5kb portion of the 11.5kb-GFP construct was made. FIG. 1 (Exhibit 1) shows the 7.6kb SacI-SacI fragment (as well as exons 5-7 boundaries and introns 5-6) and FIG. 3A (Exhibit 3) shows precisely this SacI-SacI fragment on the left (5') end of the 11.5kb-GFP transgene (in addition to introns 5-7 and exons 6-7). Additional information is provided about the 4 kb region that is on the 3' half of the 7.6 kb fragment. One of skill in the art could piece together this information to identify how the 11.5kb region was subcloned with GFP. The sequence information discussed earlier adds more information because the skilled artisan can map out all the relevant restriction enzyme sites using readily available sequence programs. A person of ordinary skill in the art could recreate the subcloning strategy with all of the information provided by the specification. Moreover, that person could subclone this fragment using any number of different strategies given that the entire sequence of the 11.5 kb region is provided. Applicants respectfully request this rejection be withdrawn.

The Examiner is invited to contact the undersigned agent at (512) 536-3081 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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Date: September 18, 2009